**Section II (Remarks)**

A. Summary of Amendment

By the present Response, claim 5 has been amended. No new matter within the meaning of 35 USC 132(a) has been introduced. Additionally, the amendment to claim 5 does not require additional search since the added method step (i.e., "[piercing] an opening in the membrane housing with the piercing element of the connector to generate a laminar flow of the gas out of the membrane housing along the sides of the opening.") is already substantially provided in claim 1 and claim 5.

B. Application Status and Purpose of Supplemental Response

In the February 24, 2006 Final Office Action, claims 1, 2, 5, and 6 were finally rejected under 35 U.S.C. 103(a) as being unpatentable over Walter (Re. 25,129) ("Walter") in view of Osborn et al. (U.S. 6,068,899)("Osborn"). Claims 3, 4, 7, and 8 were objected to as depending on rejected base claims (i.e., claims 1 and 5, respectively).

Applicant's Response to the February 24, 2006 Office Action filed on April 24, 2006 provided arguments traversing the rejections of claims 1, 2, 5, and 6.

The June 1, 2006 Advisory Action indicated that Applicant's Response filed on April 24, 2006 would be entered for purposes of appeal but would NOT place the application in condition for allowance as purportedly failing to distinguish the Walter reference. Specifically, the June 1, 2006 Advisory Action stated:

> "The connector that comprises a needle cannula 16 surrounded by a tubular sheath/diaphragm 17 in Walter is taught to be sealed to provide sterility for the cannula and its outlet from bacterial contamination. The sterility is maintained by being sealed, and it is **obvious that any air (i.e. a gas) will be within the sealed sheath** and remain there until the seal is broken and that the air/gas would be sterile. **Said cannula is used to pierce a tube at the time of use, thereby releasing the air.** This feature is separate from the bag being a void of air; the **bag being without air** to prevent a liquid-gas interface is a **separate, unrelated structural component.**"

The foregoing passage characterizing Walter reveals the examiner's fundamental misunderstanding of the reference and the lack of proper basis for rejecting claims 1, 2, 5, and 6. The present Response

is provided to correct the examiner's understanding of the prior art and to secure allowance of these rejected claims.

C. Requirements of the Rejected Claims

Claims 1, 2, and 6 as currently stated in the application, and claim 5 as amended herewith, are reproduced below for the convenience of the examiner.

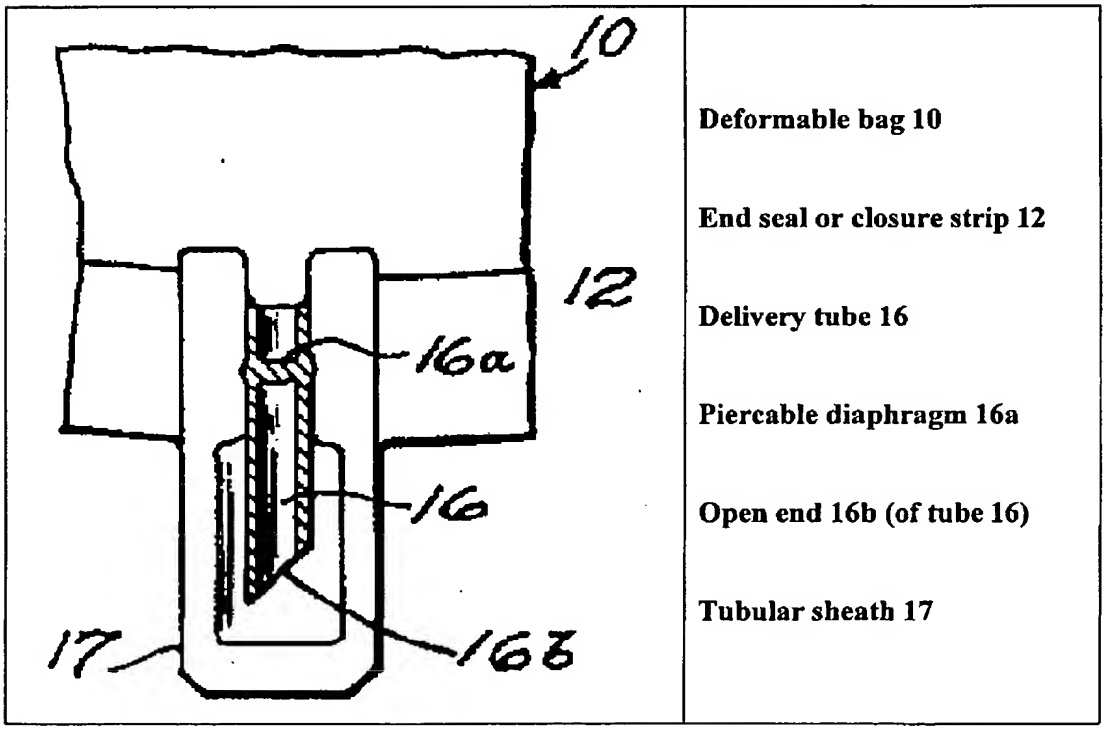
> 1. A method comprising:
> puncturing, with a piercing element of a hollow connector in fluid communication with at least one fluid, an opening of a membrane that encloses the hollow connector in a gas that is essentially sterile and at the time of puncture has a pressure of greater than about 1 atm, wherein puncturing the opening of the membrane generates a laminar flow of the gas along sides of the opening; and
> transferring the at least one fluid through the opening with the piercing element of the hollow connector.
>
> 2. The method of claim 1, further comprising attaching a container, that stores the at least one fluid, to an end of the hollow container that is opposite of an end that includes the piercing element.
>
> 5. A method comprising:
> enclosing a connector within a membrane housing;
> inserting a gas that is essentially sterile into the membrane housing at a gas pressure such that after a piercing element of the connector pierces an opening in the membrane housing, a laminar flow of the gas out of the membrane housing is generated along sides of the opening;
> sealing the membrane housing from an environment external to the membrane housing; and
> piercing an opening in the membrane housing with the connector to generate a laminar flow of the gas out of the membrane housing along the sides of the opening.
>
> 6. The method of claim 5, wherein inserting the gas into the membrane housing at the gas pressure comprises inserting the gas into the membrane housing at a gas gage pressure of greater than about 5 millibars.

D. Disclosure of Walter

Walter discloses an apparatus having multiple containers for holding a medical fluid such as blood, and then dispensing the fluid from the containers. For example, blood drawn by needle from a donor's arm flows by gravity through tubing into an ion exchange column and then into a bag 10 for storage. Walter, col. 6, lines 38-74. The bag 10 is fashioned from a thin flexible wall enabling the bag "to be completely **collapsed flatwise before filling, ridding it of air and precluding any**

**appreciable liquid-gas interface.**" Id., col. 3, lines 27-30 (emphasis added). After filling, the bag 10 is sealed for storage. Id., col. 6, lines 56-75.

The bag 10 has an inlet tube 13 and a delivery tube 16 disposed at an outlet. Id., col. 3, lines 53-73. ***Two*** **separate seals are initially associated with the delivery tube** 16: a first inner seal comprising "a piercable diaphragm of about 1 mm thickness ... at the inner end of the tube, as indicated at 16a" (col. 4, lines 1-4) and "[a] protective tubular sheath 17 ... [enclosing] the protruding portion of the delivery tube ... ." Id., col. 4, lines 1-12. This sheath affords a second and outer seal for the delivery tube [16] so that the bag [10] is subject to a double seal at this location." Id., col. 4, lines 12-14. Such double sealing arrangement is illustrated below in Figure 3 of Walter, and accompanied by the names assigned to the various numbered elements appearing in the Figure. :




**Deformable bag 10**

**End seal or closure strip 12**

**Delivery tube 16**

**Piercable diaphragm 16a**

**Open end 16b (of tube 16)**

**Tubular sheath 17**

*Manufacture* of the above-illustrated bag outlet portion is described at columns 3-4 of Walter, as reproduced in pertinent part below:

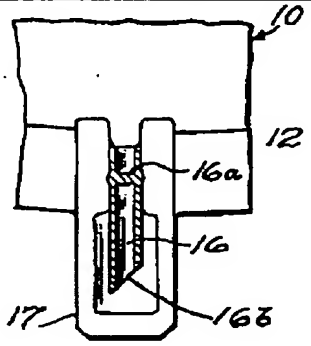
> The bag outlet is shown formed in the lower end-sealing strip 12 by a delivery to the 16 comprising a short length of the flexible tubing as for example 15 mm, or thereabouts inserted through an hermetically sealed into the seal strip 12 during the formation thereof, similarly as for the inlet tube 13. This delivery tube 16 is initially closed by a **pierceable diaphragm** of about one mm thickness formed of the like material, preferably at the inner end of the tube, as indicated at **16a**. The other and open end 16b is left protruding and may be beveled for guiding insertion of a piercing needle. A **protective tubular sheath 17** of the similar plastic is installed over and completely encloses the protruding portion of the delivery tube 16, with the inner end integrally joined with the end seal 12 of the bag, preferably simultaneously with the formation thereof, preventing bacterial contamination at the outlet. This **sheath 17 affords a second and outer seal for the delivery tube** so that the bag is subject to a **double seal** at this location.

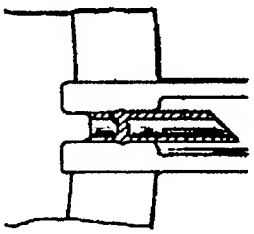
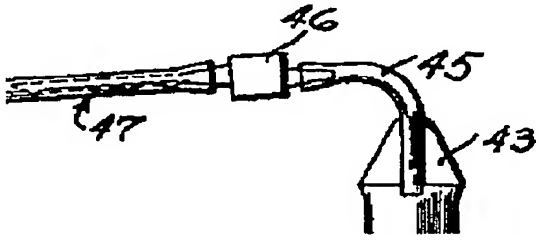
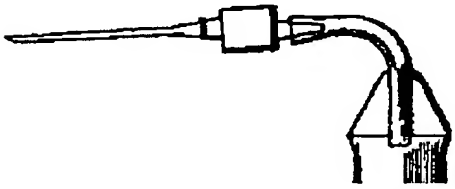
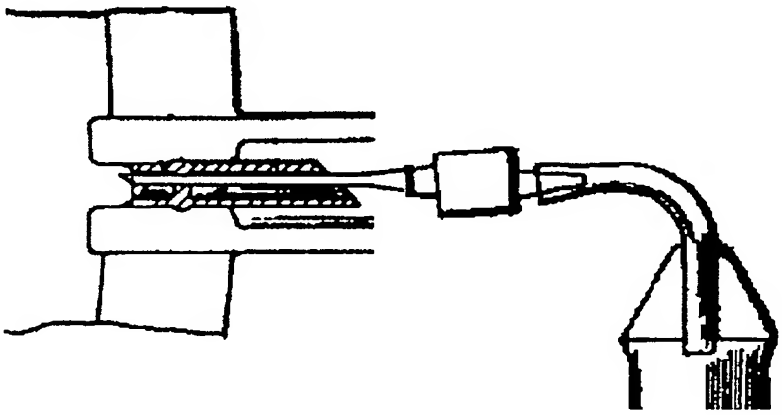
Walter, col. 3, line 71 – col. 4, line 14 (emphasis added).

Connecting *operation* of the bag of Walter is described at column 7 of Walter, as reproduced in pertinent part below:

> At the time of an infusion the **end of the protective sheath 17 is cut away from the delivery tube 16** at the bottom of the bag [10]. The **coupling needle 47** is then withdrawn from the sheathing tube 52 and is **inserted into and through the delivery tube 16** so as to **pierce the inner sealing diaphragm 16a** thereof and **provide a passage** for the blood."

Walter, col., 7, lines 5-10 (emphasis added). These critical operational steps are reproduced below.

| Step | Illustration | Description |
|---|---|---|
| 0 |  | Initial state of bag<br><br>(from Walter Figure 3) |

| Step | Illustration | Description |
|---|---|---|
| 1 |  | "the **end** of the protective sheath 17 is **cut away** from the delivery tube 16" |
| 2 |  <br>  | **"coupling needle 47** is then withdrawn from the sheathing tube 52"<br><br>(from Walter Figure 1) |
| 3 |  | **"coupling needle 47 ... is inserted into and through the delivery tube 16** so as to **pierce the inner sealing diaphragm 16a** thereof and provide a passage for the blood" |

Following piercing of the diaphragm 16a with the *separate* coupling needle 47, blood is delivered from the bag 10 through the hollow coupling needle 47, a tube 40, and an infusing needle to enter the recipient. Walter, col. 7, lines 5-32.

**Walter repeatedly speaks to the necessity of avoiding contact between air and blood.** See, e.g., Walter col. 1, lines 51 – col. 2, line 2; col. 3, lines 27-30; col. 7, line 68 – col. 8, line 2; col. 9, line 74 – col. 10, line 5; 7 claim 15. Obviously, to avoid possibility of embolism and stroke, it is essential to ensure that the blood-containing bag 10 does not contain any air when the blood contained therein is administered to the recipient.

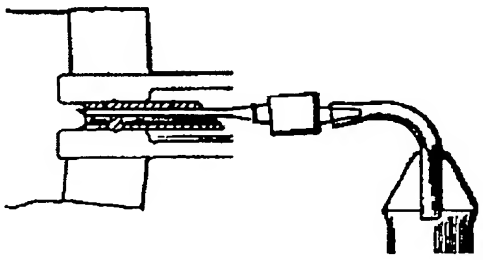
E. The Examiner's Mistaken Understanding of Walter

As noted previously, the Examiner has characterized the Walter as follows:

> "The connector that comprises a needle cannula 16 surrounded by a tubular sheath/diaphragm 17 in Walter is taught to be sealed to provide sterility for the cannula and its outlet from bacterial contamination. The sterility is maintained by being sealed, and **it is obvious that any air (i.e. a gas) will be within the sealed sheath** and remain there until the seal is broken and that the air/gas would be sterile. **Said cannula is used to pierce a tube at the time of use, thereby releasing the air.**

Such characterization indicates a faulty understanding of the disclosure of Walter in multiple respects.

First, **the cannula 16 of Walter (which is part of the claimed connector) is NOT used to pierce a tube** at the time of use; instead, a separate coupling needle 47 is used to provide piercing utility, as illustrated below..



Second, **the protective sheath 17 of Walter is NOT pierced by any "piercing element of a [] connector"** as required by claims 1, 2, 5, and 6. Instead, Walter expressly states that "the end of the protective sheath 17 is cut away from the delivery tube 16" before the coupling needle is inserted into and through the delivery tube 16 so as to pierce the inner sealing diaphragm 16a.

Third, **any "membrane" puncturing or piercing step of Walter does NOT generate any laminar flow of gas**. It is undisputed by the Examiner that the blood-containing bag of Walter is taught to be devoid of air (see, e.g., Walter col. 3, lines 27-30, providing that the bag is "to be to be completely collapsed flatwise before filling, ridding it of air and precluding any appreciable liquid-gas interface"). The pierceable diaphragm 16a of Walter is in contact with the blood-containing interior of the bag 10. See, e.g., Walter col. 7, lines 7-11 ([t]he coupling needle is 47 is then ... inserted into and through the delivery tube 16 so as to pierce the inner sealing diaphragm 16a thereof and provide a passage for the blood"). To the extent that any gas is present behind the diaphragm 17 (and this assumption is disputed by Applicants in view of the lack of any disclosure of this feature by Walter), such gas is certainly released during step (1) in which "the end of the protective sheath 17 is cut away from the delivery tube 16," and piercing of the inner sealing diaphragm by the coupling needle 47 during step (3) provides contact with the blood chamber that is clearly devoid of any air or gas.

Fourth, **the Examiner's statement "it is obvious that any air (i.e. a gas) will be within the sealed sheath" is completely baseless and lacks any support in Walter**. *Nothing* in Walter teaches or fairly suggests that air should be present behind the sheath 17. The Examiner in this respect is respectfully reminded that he must explain with specificity what areas of the references suggest the combination. See, e.g., *Ex parte Humphreys*, 24 U.S.P.Q.2d 1255, 1262 (B.P.A.I. 1992); *see also* MPEP § 2143.03 (reference(s) must teach all of the limitations of the claims to support prima *facie case* of obviousness). In view of the failure of the Examiner to identify support in Walter for the presence of any air behind the sheath – *let alone* pressurized gas as expressly required by claim 1 and inherently required by claim 5), the claim rejection would appear to be premised on mere conjecture and cannot stand.

In view of the many failings of Walter to disclose the method steps provided in claims 1, 2, 5, and 6, withdrawal of the rejection of these claims is respectfully requested.

F. Lack of Motivation to Combine Walter and Osborn (US 6,068,899)

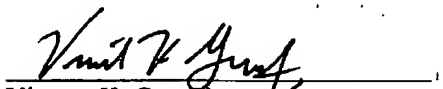
Applicant's prior characterization of Osborn and arguments as to the lack of motivation to combine Osborn with Walter to yield the claimed invention, all as stated in Applicant's Response filed on April 24, 2006, are hereby incorporated by reference. No motivation exists to combine Walter and Osborn to yield the subject matter of claims 1, 2, 5, and 6, and Osborn (directed to gas-pressurized tampon packaging) represents non-analogous art that is not properly combinable with Walter (directed to a system and method for collecting, storing, and dispensing whole blood devoid of gas) to reject these claims. The examiner therefore is requested to withdraw the rejection of claims 1, 2, 5, and 6, since the Walter and Osborn references provide no motivation for any combination yielding Applicant's claimed invention.

## CONCLUSION

The balance of the claims (namely, claims 3, 4, 7, 8 and 9-47) have already been indicated to be drawn to allowable subject matter. Claims 3, 4, 7, and 8 were objected to as depending from rejected base claims. Based on the arguments provided herein, all of the base claims on which 3, 4, 7, and 8 depend are allowable, such that withdrawal of the objections is warranted and respectfully requested.

If any issues remain outstanding, incident to the formal allowance of the application, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss their resolution, in order that this application may be passed to issue without further delay.

Respectfully submitted,



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